

of PapA that does not normally contain said peptide, and wherein said peptide is smaller than or equal to 20 amino acids in length, and a pharmaceutically acceptable carrier.

2. (Presently Amended) ~~The [An]~~ immunogenic composition ~~{as claimed in}~~ of claim 1, wherein the ~~{pili are dissociated from a}~~ pilus-producing bacteria ~~[having]~~ comprises at least one mutation that facilitates detachment of the pili from the bacteria relative to wild type strain.

3. (Presently Amended) A vaccine for preventing ~~{urinary tract infections or other microbial infections/diseases}~~ pyelonephritis ~~[if a corresponding protective epitope is inserted into the immunodominant region of PapA]~~ comprising an immunogenic composition as claimed in claim 1, wherein the peptide is inserted into the immunodominant region of PapA.

4. (Withdrawn) A process for producing pili comprising culturing a recombinant Gal-Gal pilus producing bacteria wherein said pili comprise at least one immunogenic peptide inserted into an immunodominant PapA region that does not normally contain said peptide and recovering dissociated pili.

5. (Withdrawn) A process as claimed in claim 4, wherein the bacteria has at least one mutation that facilitates detachment of the pili from the bacteria relative to a wild type strain.

6. (Withdrawn) A process for producing a vaccine comprising formulating a vaccine comprising pili produced according to claim 4 or rendering protein based haptens immunogenic by the carrier effect of fusion with PapA sequences at this location.

7. (Withdrawn) A method of treating or preventing a urinary tract infection or other microbial infections/diseases comprising administering to a subject in a need thereof a vaccine of claim 3.

8. (New) A vaccine for preventing cystitis comprising an immunogenic composition as claimed in claim 1, wherein the peptide is inserted into the immunodominant region of PapA.

9. (New) An immunogenic composition of claim 1, wherein the PapA is of a pilus type selected from the group consisting of a F71, F72, and F9 serotype.

10. (New) An immunogenic composition of claim 1, wherein the PapA is of a F13 serotype.

11. (New) An immunogenic composition of claim 9, wherein the peptide is from a pilus type selected from the group consisting of F1, F1C, F71, F72, F8, F9, F10, F11, F12 and F13 serotype. ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓

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12. (New) An immunogenic composition of claim 10, wherein the peptide is from a pilus type selected from the group consisting of F1, F1C, F71, F72, F8, F9, F10, F11, F12 and F13 serotype.

13. (New) An immunogenic composition of claim 1, wherein the peptide is between codon regions 58-74, 71-91, 57-76 and 67-77 of PapA.

14. (New) An immunogenic composition of claim 10, wherein the peptide between codon regions 58-74, 71-91, 57-76 and 67-77 of PapA.

15. (New) An immunogenic composition of claim 12, wherein the peptide is between codon regions 67-77 of PapA.

16. (New) An immunogenic composition of claim 1, wherein the peptide is selected from the group consisting of SEQ ID NO 1, SEQ ID NO 2, SEQ ID NO 3, SEQ ID NO 4, SEQ ID NO 6, SEQ ID NO 7, SEQ ID NO 8, SEQ ID NO 10, SEQ ID NO 11, SEQ ID NO 12, SEQ ID NO 13, SEQ ID NO 14, SEQ ID NO 15 and SEQ ID NO 16.

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17. (New) A vaccine of claim 3, wherein the peptide is from a pilus type selected from the group consisting of F71, F72, F8, F9, F10, F11, F12 and F13 serotype.

18. (New) A vaccine of claim 8, wherein the peptide is from a pilus type selected from the group consisting of F1 and F1C serotype.

19. (New) A vaccine of claim 3, comprising at least one peptide selected from the group consisting of SEQ ID NO 1, SEQ ID NO 2, SEQ ID NO 3, SEQ ID NO 4, SEQ ID NO 6, SEQ ID NO 7, SEQ ID NO 8, SEQ ID NO 10, SEQ ID NO 13, SEQ ID NO 14, SEQ ID NO 15 and SEQ ID NO 16.

20. (New) A vaccine of claim 8, comprising at least one peptide selected from the group consisting of SEQ ID NO. 11 and SEQ ID NO. 12.

## **Introduction**

Applicants acknowledge receipt of a non-final office action dated January 28, 2003. In the action, the examiner rejected claim 3 allegedly for non-enablement, claims 1-3 as allegedly indefinite, and claims 1-3 as allegedly obvious over Pecha *et al.* (*J. Clin. Invest.*, 83:2102-08 (1989)), in view of Steidler *et al.* (*J. Bacteriol.*, 175:7639-43 (1993)) and further in view of Baga *et al.* (*Cell*, 49:241-51 (1987)). The examiner also rejected claims 1-3 for informality reasons.

## **Status of the claims:**

In this reply, applicants amended claims 1-3 and added new claims 8-20. Support for amended claims 1-3 can be found throughout the specification, particularly on page 7, 10-12, page 9, lines 1-6 and page 10, lines 25-38. Support for new claims can be found on page 9, line 1 to page 10, line 39 (claims 3 and 8), page 6 line 22 to page 7, line 5 (claims 9 and 10), page 8, lines 24-34 and page 10, lines 25-38 (claims 11, 12, and 16-20) and page 7, lines 1-5 (claims 13-15). Upon entry of this amendment, claims 1-3 and 8-20 will be under consideration.